

Safety Data Sheet

Product Name: Enrofloxacin Flavored Antibacterial Tablets

Strength : 22.7, 68, and 136 mg

Revision No.: 00

Emergency Overview

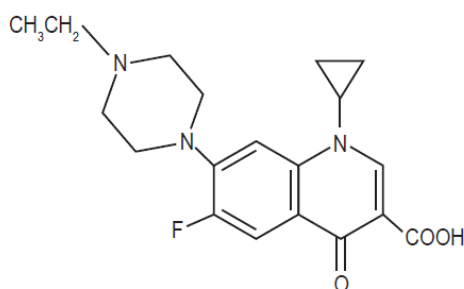
CAUTION! Colour: brown **Form:** solid tablet **Odour:** weak, musty.

Product poses little or no hazard if spilled and no unusual hazard if involved in a fire.

Section 1: Identification

Product Name: Enrofloxacin Flavored Antibacterial Tablets

Chemical Name: 1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid.



Description: Enrofloxacin is a synthetic chemotherapeutic agent from the class of the quinolone carboxylic acid derivatives. It has antibacterial activity against a broad spectrum of Gram negative and Gram-positive bacteria (See Tables I and II). It is rapidly absorbed from the digestive tract, penetrating into all measured body tissues and fluids (See Table III). Tablets are available in three sizes (22.7, 68.0 and 136.0 mg enrofloxacin).

Dosage forms and strengths:

Enrofloxacin tablets are available in the following strengths of Enrofloxacin and bottle sizes:

Flavored Tablets NDC Number	Tablet Size	Tablets/Bottle
8611700607	22.7 mg	100 Double Scored
8611700612	22.7 mg	500 Double Scored
8611700704	68.0 mg	50 Double Scored
8611700711	68.0 mg	250 Double Scored
8611700804	136.0 mg	50 Double Scored
8611700810	136.0 mg	200 Double Scored

Manufacturer / supplier identification

Company

Zydus Animal Health and Investments Limited,
Ahmedabad, India

Contact for information

Tel.: +91 2717-683954

Emergency Telephone No

Tel.: +91 2717-683951

Distributed by:

ZyVet Animal Health Inc.
Pennington, NJ 08534

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Section 2: Hazard (s) Identification

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CAUTION! Colour: brown **Form:** solid tablet **Odour:** weak, musty
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Hazard Communication (29CFR 1910.1200)

Skin Contact Eye Contact Ingestion

Acute Skin Hazards Exposure during the end use of this product is expected to be minimal. May cause irritation with symptoms of reddening and itching.

Acute Eye Hazards Exposure during the end use of this product is expected to be minimal. May cause irritation with symptoms of reddening, tearing and stinging.

Medical Conditions Aggravated by Exposure

Section 3: Composition / information on ingredients

Hazardous Ingredients:

Weight percent	Components	CAS-No.
5 - 10%	Enrofloxacin	93106-60-6
1 - 5%	Tradeseecret	
1 - 5%	Inorganic Compound	
10 - 30%	Tradeseecret	

Section 4: First -aid measures

General advice: Take off all contaminated clothing immediately.

If inhaled: Remove to fresh air. If symptoms persist, call a physician.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

Contact Number: Use the Bayer Emergency Number in Section 1

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Section 5: Fire-fighting measures

Suitable extinguishing media: Any

Specific hazards during fire fighting: Fire may cause evolution of: Carbon monoxide Carbon dioxide (CO₂)

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

Section 6: Accidental Release Measures

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

Additional advice: Avoid dust formation.

Further Accidental Release Notes Avoid dust formation.

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Section 7: Handling and Storage

Handling:

Avoid dust formation. Avoid contact with skin, eyes and clothing.

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

Storage

Dispense tablets in tight containers only. Enrofloxacin flavored tablets should be stored at 20° to 25°C (68° to 77°F), Excursions permitted to 40°C (104°F).

Section 8: Exposure controls/personal protection

Respiratory protection: Recommended Filter type: HEPA

Hand protection: Chemically resistant gloves.

Eye protection: Safety glasses

Other protective measures: Wear suitable protective equipment.

Section 9: Physical and chemical properties

Form:	Tablet
Colour:	Brown
Odour:	Weak musty
Melting point:	No data available
Density:	No data available
Bulk density:	No data available
Vapour pressure:	Not applicable
Water solubility:	No data available
pH:	No data available
Partition coefficient(n-octanol/water):	No data available
Solubility in organic solvents:	No data available
Ignition temperature:	No data available

Section 10: Stability and reactivity

Conditions to avoid: No data available

Materials to avoid: Oxidizing Agents

Hazardous reactions: None known.

Thermal decomposition: No data available

Hazardous decomposition products: Carbon monoxide, Carbon dioxide (CO₂)

Section 11: Toxicological information

Other information on toxicity:	No data is available on the product itself.
Acute oral toxicity:	Enrofloxacin LD50 rat: > 5,000 mg/kg
Tradeseecret	
LD50 rat:	> 2,000 mg/kg
Tradeseecret	
LD50 rat:	> 5,000 mg/kg
Acute inhalation toxicity:	Tradeseecret LC50 rat: > 5.05 mg/l, 4 h
Acute dermal toxicity:	Tradeseecret LD50 rabbit: > 2,000 mg/kg

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Acute toxicity (other routes of administration): Inorganic Compound LD50 intraperitoneal rat: 280 mg/kg

Skin irritation: Enrofloxacin
rabbit
Result: No skin irritation
Method: OECD Test Guideline 404
Tradeseecret
rabbit
Result: No skin irritation Method: Draize Test
Inorganic Compound
Result: Mild skin irritation
Tradeseecret
rabbit
Result: No skin irritation

Eye irritation:
Enrofloxacin

rabbit
Result: Mild eye irritation
Method: OECD Test Guideline 405
Tradeseecret
rabbit
Result: No eye irritation Method: Draize Test
Inorganic Compound
Result: Mild eye irritation
Tradeseecret
rabbit
Result: No eye irritation

Sensitisation:
Enrofloxacin

Skin sensitization guinea pig
Result: Did not cause sensitization on laboratory animals.
Method: Buehler Test
Tradeseecret
Skin sensitization guinea pig
Result: Did not cause sensitization on laboratory animals.

Genotoxicity in vitro:

Tradeseecret
Mutagenicity (Salmonella typhimurium - reverse mutation assay) Result: negative
Method: Ames test
Inorganic Compound
Ames test Result: negative
Tradeseecret Ames test Result: negative

Genotoxicity in vivo:

Tradeseecret
mouse
Result: No indication of mutagenic effects.

Pharmaceutic effects:
Enrofloxacin

Antibiotic

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Section 12: Ecological information

General advice: Do not allow to enter surface waters or groundwater. No data is available on the product itself.

Toxicity to fish: **Enrofloxacin**
Acute Fish toxicity: LC0 > 10 mg/l
Test species: Salmo gairdneri Duration of test: 96 h

Acute Fish toxicity: LC0 > 9.6 mg/l
Test species: Lepomis macrochirus (Bluegill) Duration of test: 96 h

Inorganic Compound
LC50 > 10 g/l
Test species: Danio rerio / Brachydanio rerio (zebra fish) Duration of test: 24 h

Tradeseecret
Acute Fish toxicity: LC50 > 100 mg/l
Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:
Enrofloxacin
EC0 >= 10 mg/l
Test species: Daphnia magna (Water flea) Duration of test: 48 h
Tradeseecret
LC50 > 100 mg/l
Test species: Daphnia magna (Water flea) Duration of test: 48 h

Toxicity to algae:
Tradeseecret
EC50 > 100 mg/l Duration of test: 96 h
NOEC 12.5 mg/l Duration of test: 96 h

Toxicity to bacteria:
Enrofloxacin
EC0 0.003 mg/l
tested on: Pseudomonas putida

Biodegradability:
Tradeseecret
inherently degradable

Section 13: Disposal consideration

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

Section 14: Transport information

Land transport (DOT)	Non-Regulated	
Inland waterway transport	Non-Regulated	
Railway transport	Non-Regulated	
Sea transport (IMDG)	Non-Regulated	
Air transport (ICAO / IATA cargo aircraft only)		Non-Regulated
Air transport (ICAO / IATA passenger and cargo aircraft)		Non-Regulated

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Section 15: Regulatory information

US. Toxic Substances Control Act This product is excluded from TSCA regulation by Section 3 (2)(B)(vi) when used for FDA application.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)

Components

None

SARA Section 311/312 Hazard Categories

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required

Components

None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components

None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists Weight Percent Components CAS-No.

1 - 5% Inorganic Compound

10 - 30% Tradeseecret

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Hazardous

Exempt from SARA Section 311/312

Section 16: Other information

NFPA 704M Rating

Health	1
Flammability	0
Reactivity	0
Other	0

0=Insignificant 1=Slight 2=Moderate 3=High 4=Extreme

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

References: Nil.

Issue date: 25-01-2023

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.